April 23, 2026

Medtronic Interventional Vascular, Inc.
Nikita Ciandra Vaz
Senior Regulatory Affairs Specialist
37a Cherry Hill Dr.
Danvers, Massachusetts 01923

Re: K253589
Trade/Device Name: Liberant™ RX Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEZ, KRA
Dated: November 17, 2025
Received: November 17, 2025

Dear Nikita Ciandra Vaz:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

KRINA M. PATEL -S

Digitally signed by KRINA M. PATEL -S
Date: 2026.04.23 09:28:45 -04'00'

For,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253589

Device Name
Liberant™ RX Aspiration Catheter

Indications for Use *(Describe)*
The Liberant™ RX aspiration catheter is indicated for the following:
• Removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system
• To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared:	21 April 2026
Submitter:	Medtronic Vascular 37A Cherry Hill Drive Danvers, MA 01923-5186
Applicant Contact:	Nikita Ciandra Vaz Senior Regulatory Affairs Specialist Email: nikitaciandra.vaz@medtronic.com
Alternate Contact:	Colleen Mullins Senior Principal Regulatory Affairs Specialist Email: colleen.mullins@medtronic.com
Alternate Contact:	Kim Wallner Senior Regulatory Affairs Manager Email: kim.wallner@medtronic.com
Trade Name:	Liberant™ RX Aspiration Catheter
Common Name:	Aspiration Thrombectomy Catheter
Device Classification:	Class II
Classification Name:	Embolectomy catheter, Continuous flush catheter
Classification Panel:	Cardiovascular
Regulation Number:	21 CFR 870.5150, 21 CFR 870.1210
Product Code:	QEZ, KRA
Predicate Device Name:	Export Advance™ Aspiration Catheter, cleared under K152335 on 18th September 2015 and K130536 on 16th July 2013
Reference Device Name:	Liberant Thrombectomy System, cleared under K250787 on 11th June 2025

Device Description

The Liberant™ RX aspiration catheter is a 6F Guide compatible, sterile, single use, dual lumen catheter that is 0.014" guidewire compatible. The aspiration catheter has a hydrophilic coating, a distal radiopaque tip marker, and a proximal luer-lock port (the luer).

The aspiration catheter is supplied with a preloaded stylet, 1 aspiration line, 2 locking aspiration syringes, and 1 filter cup. Packaged components are single use, provided sterile, and are sterilized using ethylene oxide.

The catheter is used for mechanical aspiration of embolic material (thrombus/debris) when connected to the aspiration pump and canister via aspiration tubing. Alternatively, the catheter is also used for manual aspiration of embolic material (thrombus/debris) when connected with supplied aspiration line and aspiration syringe. The catheter may also be used for the infusion of fluids with an infusion syringe.

Intended Use / Indications for Use

The Liberant™ RX aspiration catheter is indicated for the following:

- Removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion

Comparison to the Predicate Device

The subject device is substantially equivalent to the predicate device, which is Medtronic's own legally marketed device. There are no changes to the intended use or indications for use, design, materials, packaging, manufacturing processes, sterilization method, or shelf life.

The only difference pertains to the aspiration vacuum source, wherein an additional option for mechanical aspiration (utilizing a pump and collection canister) has been introduced as an alternative to the manual syringe method. This addition does not raise new questions regarding the device's safety or effectiveness.

Summary of Non-Clinical Data

The following non-clinical testing was performed to evaluate and demonstrate substantial equivalence between the predicate and subject device. All data met the acceptance criteria and fell within pre-determined product specifications.

<u>The following testing was performed on subject device:</u>

- Design Verification testing [Aspiration Rate, Aspiration Pressure, Particle Retrieval, Shaft Integrity, Clot Aspiration (characterization)]
- Design Validation testing (Aspiration Rate, Particle Retrieval)
- Accelerated Aging Shelf-life testing (Aspiration Rate, Aspiration Pressure, Particle Retrieval)

The following testing was leveraged from predicate device:

- Biocompatibility Evaluation
  - Cytotoxicity
  - Sensitization
  - Irritation or Intracutaneous Reactivity
  - Acute Systemic Toxicity
  - Material Mediated Pyrogenicity
  - Hemocompatibility
    - Hemolysis
    - SC5b-9 Complement activation
    - In-vivo Thromboresistance Thrombogenicity
- Packaging performance and stability
- Sterilization
- Design Verification testing [Vacuum Integrity, Evacuation Flow Rate, Particle Retrieval, Profile Dimensions (Major Profile & Minor Profile), Microlumen Tear, 2D Track and Lesion Cross, Guide Wire Lumen ID, Catheter Working Length, Proximal Shaft Tensile, Tip Tensile, Marker Band Tensile, Hub Tensile, Stylet Hub Tensile, Pressure Integrity, Air Aspiration, Proximal Shaft Crush, Proximal Shaft Buckle, Lubricity, Durability, Proximal Shaft Stiffness – Room Temp, Proximal Shaft Stiffness – Body Temp, Hub Interface]
- Design Validation testing (Tests not impacted by introduction of alternate mechanical aspiration source)
- Real time shelf-life testing (Tests not impacted by introduction of alternate mechanical aspiration source)
- Pre-clinical in vivo (non-GLP) studies

Summary of Clinical Data

No clinical testing was required for this 510(k) submission.

Conclusion from Data:

The difference between the subject and predicate devices has been evaluated through non-clinical testing, which demonstrates that the subject device Liberant™ RX aspiration catheter is substantially equivalent to the predicate device Export Advance™ aspiration catheter.